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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/741,823	12/19/2003	Soumitra S. Ghosh	660088.467	2624

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EXAMINER

REYES, HECTOR M

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/741,823	Applicant(s) GHOSH ET AL.	
	Examiner Hector M Reyes	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 in part and 10-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 in part is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/28/04 8/04/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election

The instant Application has been restricted in the following Groups as indicated in Office action dated on 10/25/04:

- I. Claims 1-9 in part, drawn to **HETEROCYCLIC** compounds, pharmaceutical acceptable salts thereof, stereoisomers thereof and multiple prodrugs thereof, and pharmaceutical compositions comprising the same, classified in multiple classes and multiple subclasses. **This group may be subjected to further restriction. A single disclosed species is hereby requested for search purpose.**

- II. Claims 1-9 in part, drawn to **NON HETEROCYCLIC** compounds, pharmaceutical acceptable salts thereof, stereoisomers thereof and multiple prodrugs thereof, and pharmaceutical compositions comprising the same, classified in multiple classes and multiple subclasses. **This group may be subjected to further restriction. A single disclosed species is hereby requested for search purpose.**

- III. Claims 10-11 in part, drawn to multiple methods of treating medical conditions or diseases using to pharmaceutical compositions comprising **HETEROCYCLIC** compounds or derivatives thereof classified in multiple classes and multiple subclasses. **This group may be subjected to**

further restriction. *A single disclosed species is hereby requested for search purpose.*

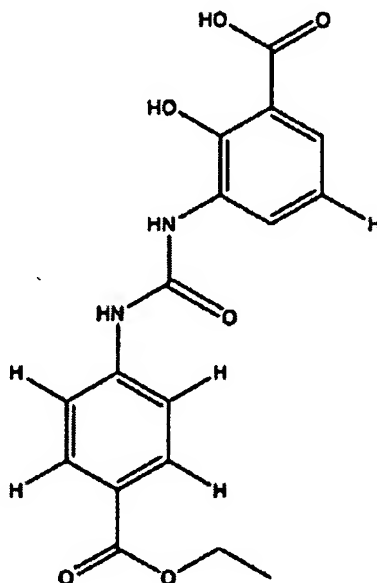
- IV. Claims 10-11 in part, drawn to multiple methods of treating medical conditions or diseases using to pharmaceutical compositions comprising **NON-HETEROCYCLIC** compounds or derivatives thereof classified in multiple classes and multiple subclasses. **This group may be subjected to further restriction. *A single disclosed species is hereby requested for search purpose.***
- V. Claims 10-11 in part, drawn to multiple methods of preventing medical conditions or diseases using to pharmaceutical compositions comprising **HETEROCYCLIC** compounds or derivatives thereof classified in multiple classes and multiple subclasses. **This group may be subjected to further restriction. *A single disclosed species is hereby requested for search purpose.***
- VI. Claims 10-11 in part, drawn to multiple methods of preventing medical conditions or diseases using to pharmaceutical compositions comprising **NON-HETEROCYCLIC** compounds or derivatives thereof classified in multiple classes and multiple subclasses. **This group may be subjected**

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**to further restriction. A single disclosed species is hereby requested
for search purpose.**

Applicant's election without traverse of group I in the reply filed on 12/07/04 is
acknowledged:

**Applicants hereby elect, without traverse, the Group I claims for examination
this time. In addition, for purpose of initial examination only, Applicants hereby elect the
species of compound 5-6 (see Table 5, page 35), having the following structure:**



The elected species however is not embraced by Group I, which is drawn to
heterocyclic derivatives. In a telephone interview, Applicant informed her intention of
electing without traverse Group II and to maintain the above elected species.

Therefore the instant Examination is drawn to:

II Claims 1-9 in part, drawn to NON HETEROCYCLIC compounds, pharmaceutical
acceptable salts thereof, stereoisomers thereof and multiple prodrugs thereof, and

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pharmaceutical compositions comprising the same, classified in multiple classes and multiple subclasses.

Status of the Claims

Claims 1-9 in part are under Examination. Claims 1-9 in part drawn to nonelected subject matter and claims 10-11 are withdraw from Examination.

Claims Objection

Claims 1-9 in part are objected because the said claims contain nonelected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, the phrases "substituted aryl", "substituted alkyl", substituted arylalkyl" and "substituted or unsubstituted homocycle" are indefinite since it is not clear what are the limitations of the compounds embraced by the said claims. Similarly, the inclusion of the terms "prodrug" and stereoisomers are indefinite. Regarding the term prodrug it is not

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indicated what are the modifications require on the general formula described in the said claim in order to generate the intended prodrug. On the other hand the nature of the stereoisomers (racemate, racemic mixture, enantiomer, diastereoisomer) intended to be claimed are not properly characterized. Since the said terms reach out to even novel yet to be discovered chemical moieties, and/or novel compounds yet to be discovered as prodrugs. Thus the claim is clearly a **reach through claim** and therefore improper.

Claim 1 is also indefinite because regarding the variable X, which is at least should be a divalent moiety there is no definition as to where the particular position of the said variable is connected to the phenyl rings. For instance let the variable X be defined as -CH₂-S-, is the sulfur part of the said definition attach to the benzoic acid or to the alternative ring? or to both? While the description of the said group may suggest that the said sulfur is connected to the benzoic acid ring, Compound III on page 14 of the specification described to opposite: a sulfur attached to the non-benzoic acid ring.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by:

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1) HCAPLUS Document number 68:114256 for Haack et al, DE 1253720 (1967). Haack discloses

- salicylic acid, 3-[(o-methylbenzyl)thio], having a registry number **18192-75-1** and
- salicylic acid, 3-(benzylthio) having a registry number **18288-97-6**.

Claims 1, 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by:

Widdowson et al, US patent 6262113, (2001). Widdowson discloses

- benzoic acid 3-[[[2-bromophenyl)amino]carbonyl]amino]-2-hydroxy having a registry number **182498-77-7** and
- benzoic acid 2-hydroxy-3-[[[(phenylamino)carbonyl]amino]-having a registry number **210358-41-1**.

Widdowson discloses that the said compounds and its compositions are useful in the treatment of diseases states mediated by the chemokine Interleukin –8 (IL-8), thus Widdowson also anticipates claim 9.

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by:

1) HCAPLUS Document Number: **137:272400**, De et al, Indian Journal of Chemistry, Section A: Inorganic Bio-Inorganic Physical, Theoretical and Analytical Chemistry, (2002) 41A(7), pp1380-1384. De discloses

- benzoic acid, 3-[[[(4-acetyl phenyl) imino] methyl]-2-hydroxy, having a registry number **462622-56-6**.

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2) HCAPLUS Document Number 132:251032, for Tarannum et al, Oxidation

Communications (1999) 22(4) pp. 519-526. Tarannum discloses:

- benzoic acid, 2-hydroxy-3-[[[(2-hydroxyphenyl) imino] methyl], having a registry number **95326-04-8**.

3) HCAPLUS Document Number 132: 202312, for Saleh , Analyst, (2000) 125(1),

pp.179-183. Saleh discloses:

- benzoic acid 2-hydroxy-3-[[[(4-methylphenyl)imino]methyl] having a registry number **201996-54-5** and
- benzoic acid, 3-[[[(4-chloro phenyl)imino]methyl]-2-hydroxy, having a registry number **259853-21-9**.

4) Widowson et al, US patent 5886044 (1998) and WO 9625157. In both documents,

Widdowson discloses:

- benzoic acid, 3-[[[(2-bromophenyl) amino]carbonyl] amino]-2-hydroxy, having a registry number **182498-77-7**.

5) Widowson et al, US patent 5780483 (1999). Widdowson discloses:

- benzoic acid, 3-[[[(2-bromophenyl) amino]carbonyl] amino]-2-hydroxy, having a registry number **182498-77-7** and

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- benzoic acid 2-hydroxy-3-[[[(phenylamino)carbonyl]amino], having a registry number **210358-41-1**.

6) HCAPLUS document number 119:139925 for Syamal et al, for Journal of Polymer Materials (1992) 9(2), pp105-111. Syamal discloses:

- benzoic acid 2-hydroxy-3-[[[2-(hydroxymethyl)phenyl]imino]methyl], having a registry number **127441-25-2**.

7) HCAPLUS document number 112: 235969 for Syamal et al, for Journal of Polymer Materials (1989) 6(3), pp175-179. Syamal discloses:

- benzoic acid 2-hydroxy-3-[[[2-(hydroxymethyl)phenyl]imino]methyl], having a registry number **127441-25-2**
- benzoic acid, 2-hydroxy-3-[[[2-hydroxyphenyl]imino]methyl], having a registry number **95326-04-8**
- benzoic acid, 2-hydroxy-3-[[[2-hydroxyphenyl]imino]methyl], having a registry number **95326-04-8**
- benzoic acid 2-hydroxy-3-[[[2-(hydroxymethyl)phenyl]imino]methyl], having a registry number **127441-25-2**.

8) HCAPLUS Document number 109:161963 for Ebisawa et al JP 63070567. Ebisawa discloses:

- benzoic acid, 2-hydroxy-3-[(phenylimino)methyl], having a registry number **67707-86-2**.

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9) HCAPLUS Document Number 102:124558 for Pastorek et al, Acta Universitatis Palackianae Olomucensis, Facultas Rerum Naturalium, (1984) 79 Chem 23), 15-20.

Pastorek discloses:

- benzoic acid 2-hydroxy-3-[[[(2-hydroxyphenyl)imino]methyl], having a registration number **95326-04-8**.

10) HCAPLUS Document number 82:38098, for Chandel et al, Journal of the Indian Chemical Society (1974), 51(7), pp. 684-685. Chandel discloses:

- benzoic acid 3-[[[(4-bromo phenyl)imino]methyl]-2-hydroxy, having a registry number **54267-70-8**.

11) HCAPLUS Document Number 64:35589 for von Plessing, Farm. Nueva, (1963) 28(321; 323) pp. 439-46; 536. von Plessing discloses:

- salicylic acid 5-chloro-3-(p-nitrobenzamido), having a registry number **7195-80-4**.

12) HCAPLUS Document Number 60:45503 for Plessing, Rev. Real Acad. Cienc. Exact., Fis. Nat. (1963) 57, pp. 655-67. Plessing discloses:

- salicylic acid, 5-chloro-3-salicylamido, having a registry number **7195-79-1**.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by:

1) HCAPLUS Document Number 124:201712 for Tait et al, Bioorganic and Medicinal Chemistry Letters (1996) 6(1) pp. 93-96. Tait discloses:

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- benzoic acid , 3-[[[4-[2-(3,4-dihydroxyphenyl)ethyl]phenyl]aminocarbonyl]-2-hydroxy, having a registry number **174362-83-5**.

2) HCAPLUS Document Number 64:35589 for von Plessing, Farm. Nueva, (1963)

28(321; 323) pp. 439-46; 536. von Plessing discloses:

- salicylic acid, 3-(p-aminobenzaamido)-5-chloro having a registry number **7180-82-7**.
- salicylic acid 5-chloro-3-salicylamido, having a registry number **7195-79-1** and
- salicylic acid 5-chloro-3-(p-nitrobenzamido), having a registry number **7195-80-4**.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (571) 272-0691. The examiner can normally be reached on M-F (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hector M. Reyes PhD JD
USPTO Reg. # P-54, 846
Au 1625
February 7, 2005

Ms. Cecilia Tsang

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